Placebo-controlled trial of indole-3-carbinol in the treatment of CIN.


Source

Department of Obstetrics and Gynecology, Louisiana State University Medical Center-Shreveport, 1501 Kings Highway, Shreveport, Louisiana, 71130-3932, USA.

Abstract

OBJECTIVE:

Most precancerous lesions of the cervix are treated with surgery or ablative therapy. Chemoprevention, using natural and synthetic compounds, may intervene in the early precancerous stages of carcinogenesis and prevent the development of invasive disease. Our trial used indole-3-carbinol (I-3-C) administered orally to treat women with CIN as a therapeutic for cervical CIN.

METHODS:

Thirty patients with biopsy proven CIN II-III were randomized to receive placebo or 200, or 400 mg/day I-3-C administered orally for 12 weeks. If persistent CIN was diagnosed by cervical biopsy at the end of the trial, loop electrocautery excision procedure of the transformation zone was performed. HPV status was assessed in all patients.

RESULTS:

None (0 of 10) of the patients in the placebo group had complete regression of CIN. In contrast 4 of 8 patients in the 200 mg/day arm and 4 of 9 patients in the 400 mg/day arm had complete regression based on their 12-week biopsy. This protective effect of I-3-C is shown by a relative risk (RR) of 0.50 ((95% CI, 0.25 to 0.99) P = 0.023) for the 200 mg/day group and a RR of 0.55 ((95% CI, 0.31 to 0.99) P = 0.032) for the 400 mg/day group. HPV was detected in 7 of 10 placebo patients, in 7 of 8 in the 200 mg/day group, and in 8 of 9 in the 400 mg/day group.

CONCLUSIONS:

There was a statistically significant regression of CIN in patients treated with I-3-C orally compared with placebo. The 2/16 alpha-hydroxyestrone ratio changed in a dose-dependent fashion.
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